



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,017	01/10/2001	Olav Lanes	U 013209-3	8104

7590 10/02/2002
Ladas & Parry
26 West 61st Street
New York, NY 10023

EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
----------	--------------

1652

DATE MAILED: 10/02/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,017

Applicant(s)

LANES ET AL.

Examiner

Elizabeth Slobodyansky

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 6-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

DETAILED ACTION

Claims 1-16 are pending.

Election/Restriction

Applicant's election with traverse of Group I in Paper No. 13 filed August 6, 2002 is acknowledged. The traversal is on the ground(s) that DNA encoding an enzyme and the enzyme should be examined together (page 2). This is not found persuasive because an enzyme and a DNA are different compounds each with its own chemical structure and function, and they have different utilities. Groups I and III are properly restricted as a process of making and product made because the product can be made by another and materially different process.

Groups I and IV are properly restricted as a product and a method of use thereof wherein a product can be used in a different method.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups II-IV, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Art Unit: 1652

Claims 1-5 are under consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The sequence search performed at the USPTO shows the discrepancy between SEQ ID NOs: 2 and 4 of the instant application and the priority application NO 2000 0163.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings filed concurrently with the application on January 10, 2001 have been objected by Draftsman, please see the attached PTO-948 form for details.

Art Unit: 1652

Specification

The disclosure is objected to because of the following: It refers to the amino acid sequences as SEQ ID NOs: 1 and 2 whereas SEQ ID NO:1 is a nucleotide sequence (page 7, line 33; page 27, line 13, for example). Further, it is unclear to what the difference between UNG1 and UNG2 is attributed.

The English spelling such as in "hydrolyses" should be replaced with the American.

Appropriate correction is required.

Claim Objections

Claim 5 is objected to because of the following informalities: "comprises" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

Art Unit: 1652

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to an uracil-DNA glycosylase (UNG) that is completely inactivated above 60° C. Claims 1 and 5 are drawn to an uracil-DNA glycosylase from any source. Claims 3 and 4 limit the source of an uracil-DNA glycosylase from “an organism adapted to a cold environment”, preferably Atlantic cod.

The claimed genus of uracil-DNA glycosylases encompasses not only the single disclosed species but many other proteins as well since some, for example mammalian proteins, commonly have allelic and splicing variants which are encoded by the same gene and different genes can encode proteins with the same function (e.g., specification, page 2, lines 18-23). All such allelic and splicing variants are encompassed by claims 1 and 3-5. Applicants disclose two representative species of the claimed genus, the uracil-DNA glycosylase from Atlantic cod having the amino acid sequences of UNG1 and UNG2, SEQ ID NOs: 2 and 4, respectively. However, absent a disclosure of the structural features common to the species within the genus, the description of two species is not sufficient as the description of the entire genus. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being an uracil-DNA glycosylase that is completely inactivated above 60° C. The functional definition of the genus does not provide any structural information or other identifying

Art Unit: 1652

characteristics commonly possessed by members of the genus that would allow one to recognize and/or predict a structure of other members of the genus. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "functional part". An enzyme can have many functions such as enzymatic, immunogenic, etc. Fragments having different functions are not necessarily the same. Without knowing the function, it is impossible to determine the metes and bounds of the claim.

Claim 3 recites "an organism adapted to a cold environment". Depending on the definition of "cold" and degree of adaptation, it can be any organism.

Art Unit: 1652

Regarding claim 4, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

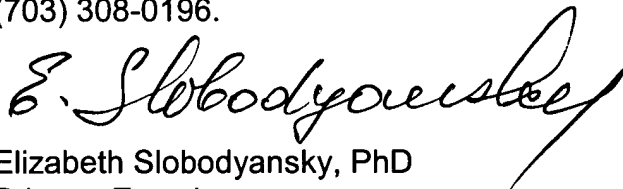
the claimed invention is directed to non-statutory subject matter.

Claims 1-5 are rejected under 35 U.S.C. 101 because they are drawn to an enzyme that is a product of Nature. Amending the claims to recite "An isolated enzyme", for example, would obviate this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner